

In the Specification

Please amend the specification as set forth below.

- 5 At page 1, prior to line 1, insert the heading --BACKGROUND OF THE INVENTION--.

At page 1, line 6, delete the heading "BACKGROUND OF THE INVENTION" and insert --BRIEF DESCRIPTION OF THE RELATED ART--.

10

Please amend the paragraph beginning at line 26 of page 1 as follows:

- Nonetheless, the use of such a sachet *in vacuo* ~~remains~~ is delicate as it is difficult to guarantee the long-term ~~tightness~~ integrity of the package, particularly during transport thereof. ~~, the least~~ Any defect in the closure of the
- 15 sachet or the presence of a ~~fragilized zone~~ weak or fragile area of the sachet ~~compromising~~ will compromise the sterile packaging of the implant.

Please amend the SUMMARY OF THE INVENTION Section of the application as follows:

20

SUMMARY OF THE INVENTION

- ~~To that end, the~~ The invention relates to a process in which, successively, the implant is placed in a flexible, gas-impermeable sachet, ~~comprising an opening adapted to be sealed,~~ a vacuum is created in the sachet ~~before it is~~ closed hermetically by sealing its opening, and the sachet sealed at an opening therein. At a time there after the implant that has been placed in the sachet *in vacuo* is sterilized by irradiation[[,]] . The invention is characterized in that it
- 25

comprises steps carried out successively before the irradiation of the implant placed in the first sachet *in vacuo* and consisting in:

[[-]] placing the sachet *in vacuo* containing the implant in a gas-impermeable envelope ~~comprising~~ having an opening adapted to be sealed,

5 [[-]] forming an inert gaseous atmosphere in the envelope, and

[[-]] closing the envelope hermetically by sealing its opening.

The packaging obtained by such a process guarantees that the ambient air, particularly the oxygen that it contains, cannot come into contact with the implant, even if the ~~tightness~~ integrity of the sachet is compromised.

10 According to other characteristics of this process, taken separately or in any technically possible combinations:

[[-]] closure of the sachet and/or of the envelope is effected by heat-sealing of their respective openings[[.]] ;

15 [[-]] the inert gaseous atmosphere formed in the envelope is constituted by argon, nitrogen or a mixture of these gaseous elements[[.]] ;

[[-]] the sachet comprises a layer of aluminum[[.]] ;

[[-]] the envelope comprises a layer of polyamide and a layer of polyethylene.

~~—in order to~~ To form the inert gaseous atmosphere in the envelope, the process comprises steps consisting in:

20 [[-]] creating a vacuum around and inside the envelope, and

[[-]] injecting an inert gas inside the envelope until the pressure inside the envelope reaches a predetermined value, strictly less than atmospheric pressure, and, after having hermetically closed the envelope, the latter is subjected to atmospheric pressure.

25 [[- the]] The inert gas is injected in calibrated manner.

~~—before~~ Before or after irradiation of the implant, the assembly formed by the implant, the sachet and the envelope is placed in a rigid packing whose internal volume is substantially equal to the volume occupied by the envelope.

~~—before~~ Before placing the assembly formed by the implant, the sachet and the envelope in the rigid packing, the envelope is folded on itself.

[[- the]] The rigid packing and the envelope ~~cooperate by complementarity of shape~~ have complementary shapes in order to immobilize the sachet containing the implant.

10 Please amend the paragraph beginning at line 17 of page 4 as follows:

The outer envelope 6 ~~presents~~ has a multi-layer structure and comprises at least one layer of polyamide and one layer of polyethylene, rendering it both flexible and gas-impermeable. Taking into account the conventional methods of manufacturing such an envelope, its impermeability is not necessarily strictly perfect.

Please amend the paragraph beginning at line 22 of page 4 as follows:

20 The inner sachet 8 also ~~presents~~ has a multi-layer structure and comprises at least one layer of ~~aluminium~~ aluminum and an inner layer of polyamide, rendering it both flexible, gas-impermeable and opaque to visible light.

Please amend the paragraph beginning at line 6 of page 6 as follows:

25

More precisely, during a step represented between instants t_0' and t_3 in Figure 5, the air initially contained in the bell 12, including that in the envelope

6, is evacuated until the pressure prevailing inside the sachet 8 attains a value of some millibars, denoted P'_{VACUUM} in Figure 5. In order not to ~~fragilize~~ harm the integrity the inner sachet 8, care is taken that the value P'_{VACUUM} is equal to or slightly greater than the value P_{vacuum} of Figure 3.

5

Please amend the paragraph beginning at line 4 of page 8 as follows:

Various variants and arrangements of the process which has ~~[[just]]~~ been described may be ~~envisaged~~ made including:

10 ~~[[-]]~~ apart from argon, the inert gaseous atmosphere of the outer envelope may be formed by nitrogen or a mixture of argon and nitrogen~~[[.]]~~ ;

~~[[-]]~~ the inner sachet may be of the same nature as the outer envelope, i.e. comprising layers of polyamide and polyethylene~~[[.]]~~ ;

~~[[-]]~~ the outer envelope may be formed by a rigid or semi-rigid shell~~[[.]]~~ ;

15 ~~[[-]]~~ the bell provided with the means for injecting the inert gas inside the outer envelope may be different from the one creating a vacuum in the inner sachet; and/or

~~[[-]]~~ the steps consisting in obtaining the inner sachet *in vacuo* on the one hand, and in obtaining the outer envelope with inert atmosphere on the other
20 hand, may be successively carried out without returning the inner sachet to the open air, on condition that a bell provided with adequate means be available.

25